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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
WILSON, MICHAEL C	
ART UNIT	PAPER NUMBER
1633	18

DATE MAILED: 12/02/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/127,738	PONCE DE LEON ET AL.	
	Examin r	Art Unit	
	Michael Wilson	1633	

-- Th MAILING DATE of this communication appears on the cover sh t with the corr spondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 September 2001* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23 and 25-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23 and 25-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicant's arguments filed 9-18-01, paper number 17, have been fully considered, but they are not persuasive. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Claim 24 has been canceled. Claims 25-30 have been added. Claims 1-23 and 25-30 are pending and under consideration in the instant office action.

Claim Rejections - 35 USC § 112

1. Claims 1-23 remain rejected and claims 25-30 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for 1) a method of obtaining avian EG cells comprising: I) isolating PGCs from an avian embryo; and ii) culturing said PGCs in a culture medium comprising LIF, bFGF and IGF, such that avian EG cells are obtained; 2) a method of making chimeric avians comprising: I) isolating PGCs from an avian embryo; ii) culturing said PGCs in a culture medium comprising: LIF, bFGF and IGF, such that avian EG cells are obtained; iii) transferring said EG cells into a recipient avian embryo; and iv) obtaining a germline and somatic cell chimeric avian, does not reasonably provide enablement for 1) identifying avian EG cells in a mixed population of avian EG cells and PGCs, 2) stably transfecting avian EG cells, or 3) a method of making germline and somatic cell chimeric avians expressing exogenous proteins or having a non-wild-type phenotype. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly

connected, to make and/or use the invention commensurate in scope with these claims for reasons of record.

For enablement purposes, EG cells are able to produce germline and somatic cell chimeras, while PGCs are able to produce germline chimeras but not somatic cell chimeras (see page 21, line 13 through page 22, line 21; especially the functional language describing avian EG cells on page 22 , line 20; see also 112/2nd below). An EG cell line is a population of cells containing EG cells.

While the specification enables obtaining EG cells as determined by obtaining germline and somatic cell chimeric chickens (page 37, line 13), the specification does not enable identifying avian EG cells within or separating EG cells from a mixed population of avian PGCs and EG cells as encompassed by the claims. Pain of record taught obtaining EG cells from Stage X embryos within a mixed population of PGCs and EG cells that provide germline and somatic cell transmission. Pain taught marker proteins found on the mixed population of cells but did not teach the pattern that distinguishes EG cells from PGCs (page 2345, col. 2). Similarly, the specification defines EG cells as being able to produce germline and somatic cell chimeras (page 22, lines 15-21) and teaches administering a mixed population of PGCs and EG cells to a recipient embryo (page 33, line 5). While the specification discusses the staining pattern of EG cells relating to SSEA-1 and 3 marker proteins, and reactivity with EMA-1 and MC-480 antibodies (page 21, line 16 through page 22, line 9), the specification does not provide adequate correlation between staining of SSEA-1 and 3 proteins, or reactivity with EMA-1 and MC-480

antibodies and the ability to produce germline and somatic cell chimeras such that EG cells could be distinguished from PGCs. EMA-1 is not specific to EG cells because it also stains PGCs (page 22, line 1). Applicant argue that MC-480 reacts strongly with mouse EG cells and avian EG cells cultured after 98 days and weakly with PGCs. Applicants argument is not persuasive because both avian EG cells and PGCs react with MC-480 (page 42, lines 4-7). The specification does not teach how "strongly" MC-480 must react for a cell to be an avian EG cell. Applicants argue PGCs become "fibroblast looking" after 3-5 passages. Applicants argument is not adequate to overcome the rejection because the metes and bounds of what applicants consider "fibroblast looking" cannot be determined or how "fibroblast looking" a cell must be to be considered an avian EG cell. It is unclear how applicants argument regarding PGCs with neuronal cell morphology correlate to the rejection regarding EG cells. Thus, the specification does not enable isolating or identifying EG cells within a mixed population of PGCs, specifically based on their expression of mouse-stage specific antigen 1, reactivity with EMA-1 or MC-480 monoclonal antibody or transfer to a suitable embryo.

The specification does not enable making chimeric avians having the EG cell or PGC phenotype as broadly claimed for reasons of record (claims 14-20 and 25-30). The method is used to determine whether germline and somatic cell chimeric avians are obtained, thus confirming the donor cells contain EG cells. The presence of EG cells in a mixed population of EG cells and PGCs is not confirmed by merely transferring the mixed population of cells to a suitable avian embryo (claim 10). Methods resulting in somatic cell chimeras that are not

germline cell chimeras encompassed by the claims do not have an enabled use. Applicants have not addressed this rejection.

Applicants argue avian EG cells can be obtained from PGCs isolated from various stages of avian embryos. Applicants argument is persuasive in that chicken EG cells are present in donor cells isolated from Stage X (Pain of record) or Stage XII-XIV (page 37) as confirmed by obtaining germline and somatic cell chimeric chickens. Applicants argument is not persuasive regarding isolating avian EG cells from a mixed population of cells for reasons above.

The specification does not enable transfecting or transforming EG cells with a nucleic acid for reasons of record (claims 12-13, 17-19 and 23). The only disclosed purpose for transfecting avian EG cells is to make transgenic avians expressing exogenous proteins or having an altered phenotype (page 7, line 17; page 2, line 23). Applicants argue transfection of avian EG cells can be performed using methods known in the art. Applicants argument is not persuasive. While Allioli (1994) taught expressing exogenous DNA in PGCs transfected with a retroviral vector *in vitro*, Allioli did not teach the PGCs were stably transfected or that the PGCs were able to produce chimeric birds expressing exogenous protein or having an altered phenotype. Vick & Simkiss, mentioned in applicants arguments filed 11-9-18-01 and 5-22-00, cannot be found and would be considered upon submission. The specification teaches transiently transfecting PGCs with DNA encoding marker proteins (1/50 on page 43, line 7, and photographs submitted 5-22-00), but not stably transfecting PGCs (page 20, line 13). The specification and the art do not teach transfecting avian EG cells, producing a stable transfected

EG cell line (page 43, line 8), or chimeric avians functionally expressing an exogenous protein using transfected avian EG cells. PGCs transiently transfected with DNA encoding marker proteins is not adequate to overcome the dearth in the art regarding stably transfecting EG cells and producing transgenic avians expressing exogenous proteins or having an altered phenotype. Given the teachings in the specification taken with what was known in the art, it would have required one of skill undue experimentation to determine how to obtain transfected EG cells that are able to make chimeric avians expressing exogenous proteins.

Specifically, the specification does not enable transfecting EG cells with DNA encoding a therapeutic protein (claims 13 and 18), isolating an exogenous protein from the egg, systemic circulating system, body fluid or tissue of a chimeric avian (claim 19) or selecting chimeric avians with any phenotype. The state of the art at the time of filing was such that the phenotype of transgenic avians with an exogenous transgene was unpredictable (Wall of record, 1996, Theriogenology, Vol. 45, pages 57-68; para. bridging pages 61-62). The specification does not provide adequate guidance for one of skill to reasonable predict that the DNA encoding exogenous proteins would be functionally expressed in transgenic avians, where exogenous protein would be expressed in transgenic avians or that the exogenous protein would have a therapeutic effect. Given the unpredictability in the art taken the teachings provided, the specification does not enable transfecting EG cells with DNA encoding a therapeutic protein or determining whether exogenous protein would be expressed in the egg, systemic circulating system, body fluid or tissue of a chimeric avian.

New claims 25 and 26 require improving the method of making germline or somatic chimeric avians. The specification does not teach how the method is improved over other methods or what applicants consider an improvement. As such, claims 25 and 26 are not enabled as written.

New claims 27-30 require culturing PGCs for at least 14 days. The specification teaches the culture media used to maintain PGCs for at least 14 days contains LIF, bFGF, IGF and SCF (page 10, line 1). The specification does not any other method of culturing PGCs for at least 14 days. Therefore, claims 27-30 are not enabled as broadly written, and LIF, bFGF, IGF and SCF are essential to culture avian PGCs for at least 14 days.

2. Claims 1-23 remain rejected and claims 25-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for reasons of record.

Applicants argue the specification distinguishes avian PGCs from avian EG cells in that avian EG cells stain positive for MC-480 (as well as SSEA-1, SSEA-3 and EMA-1 also found of PGCs) and provide germline and somatic cell transmission upon implantation into recipient embryos while avian PGCs do not stain positive for MC-480 and do not provide somatic cell transmission (page 21, line 13 through page 22, line 21). Applicants argument is not persuasive because PGCs stain positive for MC-480. It cannot be determined what amount of positive staining distinguishes PGCs and EG cells. Therefore, the metes and bounds of cells that are EG

cells within a population of PGCs cultured for a period of time in the presence of LIF, bFGF, SCF and IGF are avian EG cells cannot be determined.

Claim 3 remains indefinite because the phrase "said minimum amounts" lacks antecedent basis. Claim 2 says "minimal" amounts.

Claims 25 and 26 are indefinite because the preamble is not commensurate in scope with the body of the claim. The preamble states the claim is directed toward an improved method, but the body of the claim does not recite how the method is improved.

Claims 25 and 26 are indefinite because it is unclear if "such PGCs" in (ii) are the PGCs of (i) or some other PGCs.

Claim 25 is indefinite because it is unclear if "said PGCs" in (iii) are the PGCs of (i) or (ii).

Claim 25 is indefinite because the claim does not result in obtaining germline chimeric avians as in the preamble of the claim.

Claim 25 is indefinite because "the desired phenotype" lacks antecedent basis and because the term "desired" has variable meanings in the art and is not defined in the specification. As such the metes and bounds of the phenotypes encompassed by the claims cannot be determined.

Claims 26 and 30 are indefinite because "said cultured population of primordial germ cells" (iii) lacks antecedent basis in the claims.

Claims 26 and 30 are indefinite because "said isolated, purified PGCs" (iv) lacks antecedent basis in the claims.

Claims 26 and 30 are indefinite because "said recipient embryo" (v) lacks antecedent basis in the claims.

Claims 26, 28 and 30 are indefinite because avians do not express a phenotype. They can display or have a phenotype.

Claim 27 is indefinite because "the EG cells" lacks antecedent basis.

Claims 28 and 29 are indefinite because "said purified PGCs" (iii) lacks antecedent basis in the claims. It is unclear if the PGCs are the PGCs of (i) or (ii).

Claim Rejections - 35 USC § 102

3. Claims 21 and 22 remain rejected under 35 U.S.C. 102(b) as being anticipated by Chang (Chang et al., 1995, Cell Biol. International, Vol. 19, pages 143-149) for reasons of record.

For art purposes, EG cells are able to produce germline and somatic cell chimeras, and an EG cell line is a population of cells containing EG cells.

Chang taught isolating PGCs from chicken embryos and culturing the cells for 5 days in the presence of LIF, bFGF, IGF and feeder cells (page 143, col. 2, 2nd paragraph through page 144, col. 2, 2nd full paragraph; page 144, col. 2, last full paragraph). The population of cells cultured by Chang for 5 days contain EG cells as they are isolated from the heart, Stage XIII-XIV and cultured under similar conditions as disclosed in the specification.

Applicants argue the method used to obtain the cells claimed requires the absence of feeder cells and the presence of SCF while Chang taught culturing cells in the presence of feeder cells and the absence of SCF. Therefore, applicants argue Chang does not anticipate the claims. Applicants argument is not persuasive. The method of claim 1 does not materially alter the structure or function of the cells obtained as compared to the method of culturing taught by Chang because the resulting population of cells in claim 21 or 22 and in Chang both contain EG cells. Applicants state SCF is "required" (page 15, line 9), but applicants are also claiming EG cells can be obtained without SCF (claim 27). Applicants do not disclose for what SCF is required. The presence/absence of feeder cells does not to alter the cells obtained. Applicants argue claim 1 requires culturing cells for 14 days; however, claim 1 is not limited to culturing cells for 14 days. In the absence of evidence to the contrary, the population of cells obtained by Chang contain EG cells because the population of cells obtained would stain positive for MC-480 and are cultured under conditions similar to those taught in the specification. The patent office does not have the facilities for examining and comparing the method claimed with the method taught by Chang in order to establish the method of Chang results in a population of cells that does not contain EG cells. The burden is upon the applicant to prove that culturing the cells in the absence of SCF and presence of feeder cells results in a population of cells that do not contain EG cells and to establish patentable differences between the cells obtained in the instant application and those obtained by Chang. See Ex parte Phillips, 28 USPQ 1302, 1303 (BPAI

1993), In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray, 10 USPQ2d 1922, 1923 (BPAI 1989).

It is noted if applicant provide adequate proof that the presence of SCF and the absence of feeder cells are essential to obtain EG cells, the scope of the enablement rejection would be altered to include the presence of SCF and the absence of feeder cells in the culture conditions required to obtain EG cells.

4. Claims 1, 3-11, 14-16 and 20-22 remain rejected under 35 U.S.C. 102(b) as being anticipated by Pain (7-25-96, Development, Vol. 122, pages 2239-2348, UnCover online at http://uncweb.carl.org/uncover/unchome.html) as evidenced by Simkiss (Simkiss, 1994, MacLean, ed., Animals with novel genes, Transgenic birds, Cambridge Univ. Press, Cambridge England, NY, NY, pages 106-137) and under 35 U.S.C. 102(a) as being anticipated by Pain (Aug. 1996, Development, Vol. 122, pages 2239-2348) as evidenced by Simkiss (Simkiss, 1994, MacLean, ed., Animals with novel genes, Transgenic birds, Cambridge Univ. Press, Cambridge England, NY, NY, pages 106-137) for reasons of record.

Pain taught isolating cells from the blastoderm of a stage X chicken embryo, culturing the cells for more than 160 days in the presence of bFGF, IGF, SCF, LIF without feeder cells (page 2340, col. 1, line 9; page 2340, col. 1, 4th and 5th full paragraphs; page 2345, col. 2, line 10; 2341, col. 2, paragraph 4). The cells expressed EMA-1, SSEA-1 and SSEA-3 for 160 days (page 243, col. 2, last 2 sentences). Simkiss confirms the cells of Pain included PGCs by teaching stage X chicken embryos contain PGCs (page 111, Fig. 4.1, top panel). Pain taught introducing

the population of cells into stage X chicken embryos and obtaining germline and somatic cell chimeras (page 2341, col. 1, paragraph 2; page 2346, col. 2, line 8).

Applicants argue that Pain did not teach maintaining PGCs in culture in the absence of feeder cells. Applicants argument is not persuasive. Fig. 2B (page 2342) clearly shows that undifferentiated avian cells were maintained for 5 days in the absence of feeder cells (page 2340, col. 1) which is a "prolonged period of time" (claims 1, 3-5 and 9-11). It is noted that claim 14 only requires culturing the cells for a time sufficient to produce EG cells. While Pain taught a preferred method of culturing cells required feeder cells (page 2345, col. 2, line 10), Pain also taught "the cultures" were maintained with or without feeder cells (page 2341, col. 2, para. 4). Without evidence to the contrary, "the cultures" refers to all of the cultures discussed by Pain including the cells having the undifferentiated phenotype cultured for more than 35 passages cited on page 2345. Therefore, the method of Pain cannot be limited to culturing cells with feeder cells. Furthermore, the patent office does not have the facilities for determining whether the method taught by Pain that resulted obtaining EG cells for more than 160 days could be performed in the absence of feeder cells. The burden is upon the applicant to prove that culturing the cells in the absence of feeder cells under the culture conditions taught by Pain does not results in a population of cells containing EG cells maintained for 160 days. See Ex parte Phillips, 28 USPQ 1302, 1303 (BPAI 1993), In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray, 10 USPQ2d 1922, 1923 (BPAI 1989). If applicant provide adequate proof that the absence of feeder cells are essential to obtain EG cells, the scope of the enablement rejection

would be altered to include the presence of SCF and the absence of feeder cells in the culture conditions required to obtain EG cells.

Applicants argue that Pain taught including IL-11 and anti-retinoic acid antibody (ARMA) which is not in the claim. Applicants argument is not persuasive because the claims use open language. As such, the claims encompass using IL-11 and ARMA to culture.

5. Claims 21 and 22 remain rejected under 35 U.S.C. 102(e) as being anticipated by Petitte (US Patent 5,656,479, Aug. 12, 1997) for reasons of record.

Petitte taught avian EG cells isolated from the blastoderm of a stage IX-XIV chicken embryo, culturing the cells and obtaining EG phenotype (see claims 1-3 of '479). Applicants argue the method used to obtain the cells claimed requires the absence of feeder cells and the presence of SCF while Petitte taught culturing cells in the presence of feeder cells and does not describe using bFGF, SCF or IFG. Therefore, applicants argue Petitte does not anticipate the claims. Applicants argument is not persuasive. The presence/absence of SCF, bFGF and IFG cannot be determined in Petitte because the conditioned medium used to culture the cells may or may not contain SCF, bFGF and IFG (col. 6, line 6). Thus, the culture conditions used by Petitte do not materially alter the structure or function of the cells obtained as compared to the cells claimed because the resulting population of cells contain EG cells.

Claim Rejections - 35 USC § 103

6. Claims 1 and 2 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Pain (Aug. 1996, Development, Vol. 122, pages 2239-2348) as evidenced by Simkiss (Simkiss, 1994, MacLean, ed., Animals with novel genes, Transgenic birds, Cambridge Univ. Press, Cambridge England, NY, NY, pages 106-137) for reasons of record.

The basis of the rejection can be found in the previous office action. Applicants argue that Pain did not teach the combination of growth factors claimed, that Pain taught using IL-11, ARMA and feeder cells for culturing the cells. Applicants arguments are not persuasive for reasons discussed above in the 102 rejections over Pain.

Double Patenting

7. Claims 1-5, 14-16 and 20-22 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,156,569, Dec. 5, 2000 for reasons of record.

8. Claims 1 and 6-8 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,156,569, Dec. 5, 2000 in view of Pain (1996, Development, Vol. 122, pages 2239-2348) for reasons of record.

9. Claims 1-5, 21 and 22 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 4, 5, 7, 8 and 29-40 of copending Application No. 09/127,624 for reasons of record.

10. Claims 1 and 6-8 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 4, 5, 7, 8 and 29-40 of U.S. Patent No. 09/127624 in view of Pain for reasons of record.

Applicants acknowledgment of the obviousness-type double patenting is noted.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

No claim is allowed.

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-0120.

Questions of formal matters can be directed to the patent analyst, Tracey Johnson, who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-2982.

Questions of a general nature relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 305-0196.

If attempts to reach the examiner, patent analyst or Group receptionist are unsuccessful, the examiner's supervisor, Deborah Clark, can be reached on (703) 305-4051.

The official fax number for this Group is (703) 308-4242.

Michael C. Wilson

MICHAEL C. WILSON
PATENT EXAMINER